Central Adelaide Local Health Network
Research Services

NaCTA Panel Guidance - Schedule 4 & 7 Special Conditions to a Clinical Trial Research Agreement

Overview

The panel reviewing Australian clinical trial agreements (previously known as SEBS) is now a national panel known as the National Clinical Trial Agreement (NaCTA) Panel. The NaCTA Panel is comprised of representatives from all states and territories, and together with Medicines Australia have developed five Clinical Trial Research Agreements (CTRAs). From time to time, sponsors may wish to make changes to the body of the CTRAs. To make changes to the template, they will need to submit a NaCTA application. Amendments to the body of the CTRA are to be placed within Schedule 4 (CRG/Phase IV templates) and Schedule 7 (Standard & CRO templates).

If no amendments are being sought to any of the template CTRAs a NaCTA review is not required. The NaCTA Panel will consider CTRA amendments that are intended to accommodate (to an extent) company specific clauses that clarify or add to the CTRA. Please note that the NaCTA Panel will not accept amendments that:

- Are clearly contrary to, or attempt to modify, the core provisions of the CTRAs;
- Seek or delete or substantially modify the essential clauses of the CTRAs. These include the provisions surrounding Publication, Confidentiality, Intellectual Property, Governing Law and Termination;
- Merely restate (or "wordsmith") the existing provisions of the CTRAs;
- Seek to override the applicability of the CTRAs;
- Are contrary to government insurance arrangements or seek to require the Institution to have certain types of insurance arrangements that apply to the whole of the Government sector for each state.

Should you wish to make an amendment to submit to the NaCTA Panel the template is available on the Medicines Australia website, found here.

Initial Contact Point for Submissions

- **Phone:** (08) 7117 2225
- **Email:** Health.NaCTA@sa.gov.au

Meeting Dates

Submission deadlines and meeting dates for the NaCTA Panel are available on the Medicines Australia website located here.

Review Process

Step 1
Sponsor/Local Sponsor/CRG prepares a submission for review using the NaCTA template and submits to the NaCTA email address.
Step 2
Application is assigned to a meeting date and NaCTA secretariat appoints a Panel Member/State/Jurisdiction as the liaison officer for the request.
Step 3
The application is jointly discussed at the meeting.
Step 4
Panel Member liaises with Sponsor/Local Sponsor/CRG to advise the outcome of the application.
Step 5
If the Sponsor/Local Sponsor/CRG is accepts the NaCTA clauses, an approval letter is issued from NaCTA jurisdictions to endorse the clauses.